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510(k) SUMMARY K003444

MODEL WS-500
NONINVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM

1. **COMPANY INFORMATION.** *Name:* Nihon Seimitsu Sokki Co., Ltd ("Nissei").
Address: 2508-13 Nakago, Komochi-Mura, Kitagunma-Gun, Gunma-Ken, 377-0293, Japan
Phone: (011) 81-279-20-2311 *Contact:* Mr. I.Ishii, Quality Assurance Director

2. **DEVICE IDENTIFICATION.** *Trade Name:* Model WS-500 Digital Wrist Blood Pressure Monitor
Common Name and Classification Name: Noninvasive Blood Pressure Measurement System, 74 DXN

3. **PREDICATE DEVICE.** Model WS-300 Automatic Digital Electronic Wrist Blood Pressure Monitor, Nihon Seimitsu Sokki Co., Ltd. - K981702, SE decision 3/5/99.

4. **DEVICE DESCRIPTION.** *General:* The Nissei Model WS-500 is an automatic sphygmomanometer intended for measurement, including self-measurement by the patient, of blood pressure and heart rate. The method of operation is the oscillometric method and the site of measurement is the wrist. The system is microprocessor controlled and includes an air pump for automatic inflation; an electromagnetic deflation rate control valve, circuitry to detect and process minute pressure oscillations; a seven-digit LCD display of systolic and diastolic pressure readings followed by heart rate with operational status indicators; a memory function that stores the 30 most recent measurement results, an integral wrist measurement cuff; and two 1.5-volt replaceable batteries.
Operation: If occlusion of the systolic pulse is not achieved by initial pressurization, cuff pressure is automatically increased in 30mmHg increments until a proper systolic measurement can be obtained. The device employs a pressure measurement algorithm designed to detect, process, display, and store pressure readings. Pressure is dumped automatically at the end of each measurement sequence or if improper procedures such as movement occur that might result in inaccurate readings. .
Power: The Model WS-500 is powered by two AAA-size batteries. Power is shut down automatically if the unit remains idle for a period of approximately three minutes. Memorized values are retained after shut-down unless the batteries are removed.

5. **INTENDED USES.** The Model WS-500 system is indicated for the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients, age 18 and above. The product is recommended for use by patients capable of understanding written and/or oral directions in a home care environment.

6. **COMPARISON WITH PREDICATE DEVICE.** The Model WS-500 system has been compared with the Nissei Model WS-300 Automatic Digital Wrist Blood Pressure Monitor cleared under 510(k) No. K981702. The intended use of the two systems is the same. The site of measurement, principle of operation (oscillometric measurement), cuff materials, and many operating features are identical. The principal differences are that the WS-500 incorporates improved features such as an updated electromagnetic control valve and pressure/frequency converter and an expanded memory function, all designed to enhance overall performance and measurement reliability. It is concluded that there are no technologic differences between the subject and predicate devices that raise new questions concerning either safety or effectiveness.

7. **PERFORMANCE DATA.** The measurement performance of the WS-500 system has been evaluated in clinical studies conducted in accordance with ANSI/AAMI Standard SP10-1992 and found to comply fully with the accuracy criteria established in the standard. Safety testing including electrical characteristics of the system and components, life testing over 10,000 operational cycles, intra-device variability, environmental integrity under various operating and storage conditions including high and low altitude extremes, and resistance to vibration and shock has been conducted with satisfactory results. Similarly, electromagnetic compatibility has been evaluated and found to comply with relevant standards. Software verification and validation have been performed. It is concluded that the subject device complies with all applicable safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Nihon Seimitasu Sokki Co., Ltd.
c/o TÜV Product Service
Mr. Mark Job
510(k) Program Manager
1775 Old Highway 8 N.W.
Suite 104
New Brighton, MN 55112-1891

Re: K003444
Trade Name: Model WS-500 Digital Wrist Blood Pressure Monitor
Regulatory Class: II (two)
Product Code: DXN
Dated: November 3, 2000
Received: November 6, 2000

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003444

510(k) Number (if known):_____

Device Name: Model WS-500 Digital Wrist Blood Pressure Monitor

Indications For Use:

The WS-500 system is indicated for use in the noninvasive measurement of systolic and diastolic blood pressure and the determination of heart rate in adult patients, e.e., age 18 and above, in a homecare environment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER ~~PAGE IF NEEDED~~)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K003444

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

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